4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1120]

Draft Guidance for Industry on Vaginal Microbicides: Development for the Prevention of Human Immunodeficiency Virus Infection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Vaginal Microbicides: Development for the Prevention of HIV Infection." The purpose of this guidance is to assist sponsors in all phases of development of vaginal microbicides for the prevention of human immunodeficiency virus (HIV) infection. The guidance outlines the types of nonclinical studies and clinical trials recommended throughout the drug development process to support approval of vaginal microbicides.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Vaginal Microbicides: Development for the Prevention of HIV Infection." This guidance addresses nonclinical development, early phases of clinical development, phase 3 trial considerations, and safety considerations in vaginal microbicide development, including safety considerations in adolescent and pregnant populations. The guidance also provides some information on approaches for developing combination microbicide products such as drug-drug combinations, drug-device combinations containing a microbicide, or combination products containing a microbicide that are intended for multiple indications. With the recent approval of oral

emtricitabine/tenofovir for HIV pre-exposure prophylaxis (PrEP), the effect of oral PrEP on microbicide trial designs is an emerging topic. The guidance discusses this issue; however, it should be noted the pertinent sections may be revised as FDA takes into consideration evolving opinions in the prevention field as well as public comments on this topic.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing vaginal microbicides for preventing HIV transmission. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014, and the collections of information referred to in the guidance for clinical trial sponsors entitled "Establishment and Operation of Clinical Trial Data Monitoring Committees" have been approved under OMB control number 0910-0581.

III. Comments

Interested persons may submit either written comments regarding the draft guidance to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 19, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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